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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/700,505

11/05/2003

Shunji Natsuka

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EXAMINER

KIM, TAEYOON

ART UNIT

PAPER NUMBER

1651

MAIL DATE

DELIVERY MODE

07/18/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/700,505	Applicant(s) NATSUKA ET AL.	
	Examiner Taeyoon Kim	Art Unit 1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 April 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 27-35, 37 and 38 is/are pending in the application.
- 4a) Of the above claim(s) 27-35 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 37 and 38 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 27-35, 37 and 38 are pending.

Response to Amendment

Applicant's amendment and response filed on 4/30/2008 has been received and entered into the case.

Claims 1-26 and 36 have been canceled, claims 27-35 have been withdrawn from consideration as being drawn to non-elected subject matter, and claims 37 and 38 have been considered on the merits. All arguments have been fully considered.

The claim rejection under 35 U.S.C. §101 has been withdrawn due to the amendment.

The claim rejection under 35 U.S.C. §102 has been withdrawn due to the amendment.

The declaration filed on 4/30/2008 under 37 CFR 1.131 has been considered but is ineffective to overcome the Seed reference.

The evidence submitted is insufficient to establish a conception of the invention prior to the effective date of the Seed reference. While conception is the mental part of the inventive act, it must be capable of proof, such as by demonstrative evidence or by a complete disclosure to another. Conception is more than a vague idea of how to solve a problem. The requisite means themselves and their interaction must also be comprehended. See *Mergenthaler v. Scudder*, 1897 C.D. 724, 81 O.G. 1417 (D.C. Cir. 1897).

The submitted 1.131 declaration provided evidence that cDNA encoding Fuc-TVII was in possession and it has been utilized to express Fuc-TVII enzyme in cells such as COS-7, and the expression has been confirmed by flow cytometry. However, the amended claims now disclose "isolated" Fuc-TVII. It is the examiner's position that the declaration does not provide evidence that the enzyme has been isolated, rather it appears that it was expressed in cells and analyzed by flow cytometry (Exhibit H). According to Exhibit I, the enzymatic activity has been determined in vitro using COS cell extract expressing Fuc-TVII. However, this evidence does not disclose "isolated" enzyme. Therefore, it cannot be interpreted as "isolated" enzyme. Applicant is advised to submit evidence to prove that the Fuc-TVII has been isolated prior to the Seed reference to overcome the claim rejection under 35 U.S.C. §103.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 37 and 38 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Seed et al. (US 5,858,752) in view of Sasaki et al. (1994, J. Biol. Chem. 269:14730-14737).

Claims 37 and 38 are drawn to an isolated murine Fuc-TVII enzyme comprising a catalytic domain encoded by a segment identical to a polynucleotide amplified by SEQ ID NO:3 and SEQ ID NO:4 (claim 37); and the catalytic domain consisting of residue

2194 to 3085 of SEQ ID NO:1 (claim 38).

Seed et al. teach a murine Fuc-TVII enzyme, encoded from a murine Fuc-TVII cDNA, and any analog or fragment thereof (column 16, lines 34-37). Seed et al. also teach purification of Fuc-TVII polypeptide using anti-Fuc-TVII antibody (col. 13, lines 17-22).

Although Seed et al. do not particularly teach a catalytic domain of a murine Fuc-TVII enzyme, the fragments of a murine Fuc-TVII of Seed et al. comprise a fragment consisting of the catalytic domain of a murine Fuc-TVII enzyme. A person of ordinary skill in the art would deduce the sequence of the catalytic domain of a murine Fuc-TVII enzyme based from the catalytic domain of a human Fuc-TVII enzyme taught by Sasaki et al. (see Abstract).

It would therefore have been obvious for the person of ordinary skill in the art at the time the invention was made to synthesize a murine Fuc-TVII enzyme of Seed et al. comprising a catalytic domain using a recombinant DNA technology based on the catalytic domain of a human Fuc-TVII of Sasaki et al.

The skilled artisan would have been motivated to make such a modification because the catalytic domain of the enzyme is a minimum requirement for the function of enzymatic activity. Therefore, a person of ordinary skill in the art would have been synthesized a murine Fuc-TVII enzyme comprising at least a catalytic domain of the enzyme by deducing the sequence of a murine Fuc-TVII based on a human sequence of Sasaki et al.

The person of ordinary skill in the art would have had a reasonable expectation

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of success in identifying a catalytic domain of a murine Fuc-TVII enzyme and generate a murine Fuc-TVII enzyme comprising a catalytic domain because it was successfully carried out by Sasaki et al. with human Fuc-TVII enzyme.

Therefore, the invention as a whole would have been prima facie obvious to a person of ordinary skill at the time the invention was made.

Conclusion

No claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Taeyoon Kim whose telephone number is (571)272-9041. The examiner can normally be reached on 8:00 am - 4:00 pm ET (Mon-Thu).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only.

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For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Leon B Lankford/

Primary Examiner, Art Unit 1651

Taeyoon Kim

AU-1651